PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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File 85.78 7831/002
14 JUL 2004
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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

	Date of mailing *(day/month/year)* 12.07.2004
Applicant's or agent's file reference 85.84.78783/002	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/03205	25.07.2003	25.07.2002

Applicant
DIOMED INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
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Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 85.84.78783/002	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/03205	International filing date *(day/month/year)* 25.07.2003	Priority date *(day/month/year)* 25.07.2002
International Patent Classification (IPC) or both national classification and IPC A61B18/22		
Applicant DIOMED INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 11 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25.02.2004	12.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Riechel, S Telephone No. +49 89 2399-7832

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/03205

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-14 as originally filed

Claims, Numbers

1-67 received on 11.06.2004 with letter of 09.06.2004

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 2,5-8,10-12,19-21,25-28,39,42-45,50-54,58-60

   because:

   ☒ the said international application, or the said claims Nos. 2,5-8,10-12,19-21,25-28,39,42-45,50-54,58-60 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,3,4,9,13-18,22-24,29-38,40,41,46-49,55-57,61-67
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1,3,4,9,13-18,22-24,29-38,40,41,46-49,55-57,61-67
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1,3,4,9,13-18,22-24,29-38,40,41,46-49,55-57,61-67
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No opinion is established for the subject-matter of claims 2, 5-8, 10-12, 19-21, 25-28, 39, 42-45, 50-54 and 58-60 since they introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT, for the following reasons:

Independent claims 1, 35-37:

The subject-matter of independent claim 1 is based on originally filed claim 45 and on the aspect of the invention described on page 5, line 25 - page 6, line 5. Amended independent claim 1 is therefore allowable under Article 34(2) PCT. However, amended claim 1 does not contain the feature F1 of originally filed claim 1 that

F1: "in use, said laser device receives information from said delivery device".

Claims 35 and 36 are based on original claim 45, since the skilled person would understand that the delivery device can be disconnected from the laser device.

Claim 37 is based on page 5, line 25 - page 6, line 2 in combination with page 10, lines 13-20.

Dependent claims 2-34:

Claims 2-34 have been added dependent on amended claim 1.

Although the additional features introduced by dependent claims 2-34 are similar to the features of originally filed dependent claims 2-38, new feature combinations arise since amended claim 1 does not contain F1. Some of the resulting new feature combinations had originally not been disclosed, see for example amended claim 12 (the laser system updates the information indicating the intended use of the connected delivery device). In the detailed description of the embodiments (page 8-14) the additional features introduced by dependent claims 2-34 had only been disclosed in combination with F1, see page 8, line 25. Furthermore it is noted that a skilled person would not seriously consider an arbitrary combination of features from the various aspects of the invention (page 2, line 9 - page 8, line 3), since some of them obviously represent mutually excluding aspects of the invention.

Since the applicant has not indicated a basis for amended claims 2-34, they are

considered to add subject-matter unless a basis can be determined, ie unless

- their features had clearly been disclosed in combination with the features of amended claim 1 (amended claims 13-16, 34)
- their features clearly relate to all aspects of the invention (amended claims 4, 9, 17)
- their features contain or necessarily imply F1 (amended claims 3, 18, 22-24, 29-33).

Therefore claims 2, 5-8, 10-12, 19-21 and 25-28 are considered to add subject-matter, contrary to Article 34(2)(b) PCT.

Method claims 38-67:

Amended claims 38-67 have been formulated in equivalence with amended claims 1-34. Accordingly claims 39, 42-45, 50-54 and 58-60 are considered to add subject-matter, contrary to Article 34(2)(b) PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: EP-A-0 473 987 (ZEISS STIFTUNG ;SCHOTT GLASWERKE (DE)) 11 March 1992 (1992-03-11)

D6: US 2002/034365 A1 (VOGELSANG HORST) 21 March 2002 (2002-03-21)

Claim 1:

The document **D1** is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):

a method and an apparatus for the contactless (column 6, lines 1-4) optoelectronical recognition of exchangeable delivery devices 4, 5 connectable to a medical laser (figure 1; column 1, lines 1-17). The delivery devices comprise an optical fibre 5 for delivering said laser radiation and a connector 4 equipped with a colour code. The laser head 6 contains an optoelectronical recognition system for reading the information of the colour code (column 3, lines 37 -49). When, in use, a delivery device is connected to the laser the laser receives said information from

the applicator.

The subject-matter of claim 1 differs from this known system by the feature F2 that,

F2: in use, the laser updates the information on said read/write device.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to distinguish used from unused delivery devices. The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT), since none of the available prior art addresses the problem of distinguishing used from unused delivery devices or indicates that the information provided on the fibre might, in use, be modified by the laser system.

Claims 35-38:
The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 35 -38 as follows:
Claims 35 and 36 are directed to a laser device per se and a delivery device per se, respectively, both containing feature F2. The subject-matter of claim 36 is furthermore clearly distinguished from the disclosure of D6 by feature F2.
The subject-matter of claim 37 contains all the features of claim 1 and is therefore also new and inventive.
Claim 38 refers to a method of operating a laser system and is equivalent to claim 1.

Dependent claims:
Claims 3, 4, 9, 13-18, 22-24, 29-34, 40, 41, 46-49, 55-57, 61-67 are dependent on claim 1 or 38, respectively, and as such also meets the requirements of the PCT with respect to novelty and inventive step.

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Claims

1. A laser system comprising:

a laser device for emitting laser radiation; and

a delivery device adapted to connect, in use, to said laser device for delivering said laser radiation, said delivery device comprising a read/write device for storing information;

wherein, in use, said laser device updates said information on said read/write device.

2. A laser system as claimed in claim 1, wherein said read/write device comprises an AC or RF identification tag or transponder.

3. A laser system as claimed in claim 1 or 2, wherein, in use, said laser device receives information from said delivery device.

4. A laser system as claimed in claim 1, 2 or 3, wherein said delivery device comprises an optical fibre.

5. A laser system as claimed in any preceding claim, wherein said laser device includes a detector for detecting the connection of said delivery device.

6. A laser system as claimed in claim 5, wherein, in use, said laser device interrogates said delivery device after said detector indicates that said delivery device has been connected to said laser device.

7. A laser system as claimed in any of claims 1 to 5, wherein said laser device interrogates said delivery device.

8. A laser system as claimed in claim 6 or 7, wherein said laser device interrogates said delivery device in a contactless manner.

9. A laser system as claimed in any preceding claim, wherein said information is encoded on, embedded within or otherwise stored with said delivery device.

10. A laser system as claimed in any preceding claim, wherein said information indicates the type of said delivery device.

11. A laser system as claimed in any preceding claim, wherein said information indicates the state, usage, expiry date, age or model of said delivery device.

12. A laser system as claimed in any preceding claim, wherein said information indicates the intended use or function of said delivery device.

13. A laser system as claimed in any of claims 2-12, wherein said laser device comprises an AC or RF identification reader for reading said AC or RF identification tag or transponder.

14. A laser system as claimed in claim 13, wherein, in use, said delivery device transmits or returns a signal to said AC or RF identification reader.

15. A laser system as claimed in any preceding claim, wherein said delivery device receives, in use, a power or electromagnetic pulse.

16. A laser system as claimed in any preceding claim, wherein said delivery device receives, in use, AC or RF energy, stores said energy, and transmits back to said laser device data or information using said stored energy.

17. A laser system as claimed in any preceding claim, wherein said laser device comprises a SMA-905 connector for receiving an optical fibre.

18. A laser system as claimed in any preceding claim, wherein in a mode of operation said laser device prevents operation with said delivery device upon receiving information from said delivery device.

19. A laser system as claimed in any preceding claim, wherein in a mode of operation said laser device prevents operation with said delivery device if said laser device does not receive any information from said delivery device.

20. A laser system as claimed in any preceding claim, wherein said laser device prevents operation if a

delivery device known per se is connected to said laser device.

21. A laser system as claimed in any preceding claim, wherein the delivery device known per se does not transmit information to said laser device.

22. A laser system as claimed in any of claims 3-21, wherein in a mode of operation said laser device prevents operation with said delivery device if said laser device receives information from said delivery device and wherein said information indicates a predetermined parameter.

23. A laser system as claimed in claim 22, wherein said parameter indicates the usage of the delivery device.

24. A laser system as claimed in claim 22 or 23, wherein said parameter indicates the sterility of the delivery device.

25. A laser system as claimed in claim 22, 23 or 24, wherein said parameter indicates the type of the delivery device.

26. A laser system as claimed in any of claims 22-25, wherein said parameter indicates an expiry date of the delivery device.

27. A laser system as claimed in any preceding claim, wherein said laser device may be enabled and/or disabled remotely.

28. A laser system as claimed in claim 27, wherein said laser device may be enabled and/or disabled via a telephone link, serial interface or via the internet.

29. A laser system as claimed in any preceding claim, wherein said laser device further comprises a visual display, said display being adapted to provide the user with information received from said delivery device.

30. A laser system as claimed in any preceding claim, wherein in a mode of operation said laser device receives information from said delivery device and, in response to the information received, sets the power of laser radiation to be transmitted to said delivery device.

31. A laser system as claimed in any preceding claim, wherein in a mode of operation said laser device receives information from said delivery device and, in response to the information received, sets the pulse width of laser radiation to be transmitted to said delivery device.

32. A laser system as claimed in any preceding claim, wherein in a mode of operation said laser device receives information from said delivery device and, in response to the information received, sets the interval between pulses of laser radiation to be transmitted to said delivery device.

33. A laser system as claimed in any preceding claim, wherein in a mode of operation said laser device receives information from said delivery device and, in response to the information received, sets the duration that laser radiation is to be transmitted to said delivery device.

34. A medical laser device comprising a laser system as claimed in any preceding claim.

35. A laser device for emitting laser radiation which, in use, updates information stored on a delivery device which comprises a read/write device for storing said information.

36. A delivery device adapted to connect, in use, to a laser device for delivering laser radiation, wherein said delivery device comprises a read/write device for storing information which, in use, is updated by the laser device.

37. A laser system comprising:

a laser device for emitting laser radiation; and

a delivery device adapted to connect, in use, to said laser device for delivering said laser radiation, said delivery device comprising a read/write AC or RF identification tag or transponder for storing information;

wherein, in use, said laser device updates said information on said AC or RF identification tag or transponder.

38. A method of operating a laser system comprising the steps of:

providing a laser device; and

connecting a delivery device comprising a read/write device for storing information to said laser device;

wherein said laser device updates said information on said read/write device.

39. A method as claimed in claim 38, wherein said read/write device comprises an AC or RF identification tag or transponder.

40. A method as claimed in claim 38 or 39, wherein said laser device receives information from said delivery device.

41. A method as claimed in claim 38, 39 or 40, wherein said delivery device comprises an optical fibre.

42. A method as claimed in any of claims 38-41, wherein said laser device detects the attachment of said delivery device.

43. A method as claimed in claim 42, wherein said laser device interrogates said delivery device after detecting the attachment of said delivery device.

44. A method as claimed in any of claims 38-42, wherein said laser device interrogates said delivery device.

45. A method as claimed in claim 43 or 44, wherein said laser device interrogates said delivery device in a contactless manner.

46. A method as claimed in any of claims 38-45, wherein said information is encoded on, embedded within or otherwise stored with said delivery device.

47. A method as claimed in any of claims 38-46, wherein said laser device receives information from said delivery device and displays said information for the user.

48. A method as claimed in any of claims 38-47, wherein said laser device receives information from said delivery device indicating the usage of the delivery device.

49. A method as claimed in any of claims 38-48, wherein said laser device receives information from said delivery device indicating the sterility of the delivery device.

50. A method as claimed in any of claims 38-49, wherein said laser device receives information from said delivery device indicating the type of the delivery device.

51. A method as claimed in any of claims 38-50, wherein said laser device receives information from said delivery device indicating the expiry date of the delivery device.

52. A method as claimed in any of claims 38-51, wherein in a mode of operation said laser device prevents operation with said delivery device if said laser device does not receive any information from said delivery device.

53. A method as claimed in any of claims 38-52, wherein said laser device prevents operation if a delivery device known per se is connected to said laser device.

54. A method as claimed in any of claim 53, wherein the delivery device known per se does not transmit information to said laser device.

55. A method as claimed in any of claims 40-54, wherein in a mode of operation said laser device prevents operation with said delivery device if said laser device receives information from said delivery device and wherein said information indicates a predetermined parameter.

56. A method as claimed in claim 55, wherein said parameter indicates the usage of the delivery device.

57. A method as claimed in claim 55 or 56, wherein said parameter indicates the sterility of the delivery device.

58. A method as claimed in claim 55, 56 or 57, wherein said parameter indicates the type of the delivery device.

59. A method as claimed in any of claims 55-58, wherein said parameter indicates an expiry date of the delivery device.

60. A method as claimed in any of claims 38-59, wherein in a mode of operation said laser device is enabled and/or disabled remotely.

61. A method as claimed in any of claims 38-60, wherein said delivery device receives a power or electromagnetic pulse.

62. A method as claimed in any of claims 38-61, wherein said delivery device receives AC or RF energy, stores said energy, and transmits back to said laser device data or information using said stored energy.

63. A method as claimed in any of claims 38-62, wherein said laser device receives information from said delivery device and, in response to the information received, configures the operation of said laser device.

64. A method as claimed in claim 63, wherein, in response to the information received, said laser device sets the power of laser radiation to be transmitted to said delivery device.

65. A method as claimed in claim 63 or 64, wherein, in response to the information received, said laser device sets the pulse width of laser radiation to be transmitted to said delivery device.

66. A method as claimed in claim 63, 64 or 65, wherein, in response to the information received, said laser device sets the interval between pulses of laser radiation to be transmitted to said delivery device.

67. A method as claimed in any of claims 63-66, wherein, in response to the information received, said ~~laser~~ device sets the duration that laser radiation is to be transmitted to said delivery device.